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October 25, 1999

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The Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. Street S.W.
Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Maintains cellular health.
- (2) The antigenic properties promote healthy cellular division, function, and growth.
- (3) The bovine spleen PMG™ extract in Spleen PMG appears to neutralize the circulating antibody, thereby contributing to the maintenance of cellular health.
- (4) Spleen PMG improves calcium absorption.
- (5) Spleen PMG enhances metabolic efficiency.
- (6) Magnesium functions as a co-factor, assisting enzymes in catalyzing many chemical reactions.
- (7) Magnesium functions in such reactions as nerve conduction and nerve excitability; transfer of energy, muscular activity; and many other specific processes.
- (8) Magnesium and calcium play an important role in human metabolism.
- (9) Spleen PMG helps support the spleen's filtration and cleansing of the blood, the reabsorption of useful materials from the blood, and the synthesis of hemoglobin which is vital in providing oxygen to the tissues.
- (10) Spleen PMG provides nutritional ingredients and support for the spleen.

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These statements are made for a dietary supplement containing a proprietary blend of bovine spleen PMG™ extract, and magnesium citrate. Other ingredients include calcium lactate, cellulose, and calcium stearate. The name of the product is Spleen PMG®.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden
Standard Process Inc.

